



RON CHAPMAN, MD, MPH
Director & State Health Officer

Vital Statistics Advisory Committee (VSAC)
Vital Records Protection Advisory Committee (VRPAC)
Joint Meeting
Meeting Minutes for Wednesday, May 8, 2013
9:00 AM



EDMUND G. BROWN JR.
Governor

ATTENDEES:

Convener: Krista Christian, MBA, Chief, Vital Statistics Unit

Committee Members:

Present: Jonathan Teague, MCRP, Deborah Williams

Phone: David Grant PhD, Matthew Sundquist

California Department of Public Health (CDPH) Staff:

Present: Laura Lund M. A., Science Advisor, Cindy Tanaka-Fong,
Laurie Taylor, Karen Roth

Public Attendees:

Present: Dr. Mary Karpos, Linda Remy PhD, Sun Lee

CALL TO ORDER: The meeting was called to order at 9 A.M.

A/B. WELCOME/INTRODUCTIONS: Krista announced that this was a public meeting conforming to the Bagley-Keene open meeting act. Members of the public are allowed to attend and welcome to participate at the end of the meeting.

Krista informed everyone that the meeting was being recorded to assist with minute taking and introduced CDPH staff.

Research protocols are available for review on our Department's SharePoint site. Protocols are uploaded up to 3 weeks prior to the VSAC meeting and members were encouraged to download and review them early to avoid issues.

We currently have 7 members on the committee and we are still recruiting for committee members for VSAC/VRAC. We would like to include recommendations from our existing committee members. Interested parties can contact Krista Christian at (916) 552-9873 or you can e-mail me at krista.christian@cdph.ca.gov.

C. APPROVAL OF MINUTES FROM THE PREVIOUS MEETING:

Deborah Williams motioned to approve the March 13, 2013 meeting minutes. Jonathan Teague seconded the motion. All Committee members voted to approve the minutes. There were no oppositions.

D. VSAC RECOMMENDATIONS FROM THE PREVIOUS MEETING:

Attachment 1, the State Registrar's Response to VSAC Recommendations, is a recap of recommendations from the last meeting.

Twelve projects were reviewed. Ten projects were recommended approval adopted by the State Registrar. The committee requested additional information on one project from the principal investigator and one project the committee deferred to the State Registrar for the decision on the release.

E. NEW BUSINESS:

The following project was reviewed at the March 13th VSAC meeting and the committee members sought additional information before recommending approval of the protocol.

Project Title: "Longitudinal Study of Hospital Outcomes for California Children"

Principal Investigator(s): Linda Remy, PhD, UCSF Family Health Outcomes Project (FHOP)

Project Type: Continuing Project with Changes to the Protocol

CPHS Approval: Approved

Project No.: 09-06-02

Expiration: April 5, 2013

File(s) Requested: 2010-2011 Birth Statistical Master File (selected variables), 2010-2011 Death Statistical Master File (selected variables), 2010-2011 Fetal Death Statistical Master File (selected variables)

Requested Identifiers: BSMF - Name, Certificate Number, Address, DSMF - Name, Certificate Number, SSN, Address, FDSMF - Name, Certificate Number

Personal Contact: No

Identifiers Released: No

- Dr. Remy provided clarification to the responses to questions raised during the protocol review in the March 13, 2013 VSAC meeting. They did not ask for the SSN for the birth files as they understood this was not available. They have asked for SSN for the death files.

- They have not constructed a file using SSN to link the birth file. They do not use SSN, but encrypt and discard the original SSN variable. The resulting variable is called SSNC. Under the methodology, each file must have SSNC encrypted using the same algorithm.
- FHOP has never released a linked data file.
- FHOP is not part of Maternal, Child, and Adolescent (MCAH) Program. FHOP is a unit of Family and Community Medicine at the University of California, San Francisco.
- FHOP has had a cooperative agreement with MCAH for twenty years. The agreement required FHOP to develop data methods of analysis of vital records and OSHPD data to produce state and jurisdiction-level reports to monitor health status and outcomes.
- The current protocol has been approved annually with minor modifications since 1996. The primary modification generally was to add years of data and to describe specific uses of the data for various research projects over time that supported their focus.
- Various organizations have provided funding for their work. They have been fortunate to have cooperative agreements with MCAH and HISP, and grants from private foundations and the Federal government, all under the same protocol.
- They do not represent the State or any of its programs. They are not part of MCAH. They are part of the University of California, and accountable through the UC system
- MCAH does not manage or oversee the FHOP data acquisition and never had custody of the data.
- FHOP does not conduct research in terms of developing a research question. They develop methods to monitor public health access and outcomes using complex population-health databases that change over time and have significant data quality problems. They translate these methods into SAS macros that result in products to monitor public health.
- Other examples of their methodological work and resulting products include: developing methods to bridge changing definitions of race/ethnicity across agencies; generating statistical information with small numbers; developing a master geography file to identify the community where each ZIP that has been issued for California is/was located so that cases can be assigned to their correct geography; developing a crosswalk between text strings; developing a crosswalk between codes that identify the same hospital; assigning different text strings to spell a city name correctly; and writing SAS macros to produce these products.

This type of work does not have a research hypothesis. The work is directed toward overcoming the significant problems of managing large, complex public health datasets. The methods are made available to other researchers in the form of SAS data sets, and the products they develop can be applied on behalf of any population.

- Most of the final datasets are completely de-identified, small summary files.

There were 2 concerns that were brought up during the March meeting: One was the use of SSN, in which an explanation was provided. The other was allowing an open-ended use of the data. Once linked, the data could be used for multiple projects to be described over time, but there is no indication of what these projects would be.

Linda told the committee that because the files are so enormous, they do not save the files permanently, but only create views of the files to link with a given product. The concern was about the data being disseminated to other projects, but Dr. Remy clarified this point.

VSAC Recommendation: Approve the data request.

VSAC Motion: Jonathan Teague motioned to recommend approval of the data request. Deborah Williams seconded the motion.

VSAC Vote: Committee members all voted in favor of recommending approval. There were no oppositions. There was one abstention. Motion carried.

The first project reviewed by the Committee was:

Project Title: "Study of Social Development in Toddler Twins"

Principal Investigator(s): Theodore Jacob, PhD, Veterans Affairs Palo Alto Health Care System

Project Type: Continuing Project with Changes to the Protocol

CPHS Approval: Pending

Project No.: 12-04-0137

Expiration: Pending CPHS Approval

File(s) Requested: 2012 Birth Statistical Master File (select variables), 2012 Infant Deaths (select variables), and Special Run -

1/1/12-9/30/12 (select variables), Special Request

Requested Identifiers: Birth Statistical Master File, Infant Deaths
Special Run - 1/1/12-9/30/12 (all files requesting Name, Certificate
Number, Address) Special Request (select variables)

Personal Contact: No

Identifiers Released: No

History: Previous Data Request

VSAC Discussion: Jonathan noticed the protocol stated data would be coming from OSPHD; however, this appeared to be a clerical error, since the data would be coming from HIRS. One committee member raised concerns about security measures. Clarification was provided. The project will select a random sample of California twins as representative of the larger California population but survey materials have only been created in English. They are eliminating 20% of parents in California. A question was raised on if we ask for justification for not having Spanish translation? Krista said we can suggest this to the requestor but the committee is not responsible for evaluating research protocols, but instead looks at whether or not the data is being released for a valid purpose. A committee member mentioned he thought that this was the job of the committee was to evaluate the scientific validity or rigor of these projects. Laura commented that the committee acts as a gatekeeper for projects in which requesters state scientific research is being conducted when the primary intent of the project is for another purpose and those who are genuinely conducting scientific research. A poorly designed scientific study, if valid, would not be a reason to deny release of the data.

VSAC Recommendation(s): Approve the data request with the suggestion to have materials translated in Spanish.

VSAC Motions: Jonathan Teague motioned to recommend approval of the data request. Matthew Sundquist seconded the motion.

VSAC Vote: Committee members voted in favor of recommending approval of the data request. There were no oppositions. Motion carried.

The second project reviewed by the Committee was:

Project Title: "Short Inter-pregnancy intervals and Risk of Autism Spectrum Disorders"

Principal Investigator(s): Lisa Croen, Kaiser Permanente

Project Type: New Project

CPHS Approval: Approved

Project No.: 12-10-0821

Expiration: January 3, 2014

File(s) Requested: 2000-2009 Birth Statistical Master File (selected variables), 2000-2009 Birth Cohort File (selected variables)

Requested Identifiers: BSMF: Name, Certificate Number, Address; BC: Name, Certificate Number

Personal Contact: No

Identifiers Released: No

History: New Research Project

VSAC Discussion: There was concern about the requestor receiving SSN.

VSAC Recommendation(s): Approve the data request with the caveat that we would contact the PI that SSN and marital status would not be released. The PI was contacted by e-mail about SSN but this was not included in discussion.

VSAC Motions: Jonathan Teague motioned to recommend the approval of the data. Deborah Williams seconded the motion.

VSAC Vote: The Committee members all voted in favor of recommending approval of the data request. There were no oppositions. Motion carried.

The third project reviewed by the Committee was:

Project Title: "Advanced Illness Management Pilot Program: Cost and Utilization of Care among AIM Enrollees and Controls"

Principal Investigator(s): Sara Robinson, Sutter Health

Project Type: New Project

CPHS Approval: Requested

Project No: Pending CPHS Approval

Expiration: Pending CPHS Approval

File(s) Requested: 2009-2010 Death Statistical Master File (select variables)

Requested Identifiers: Name, Address, SSN

Personal Contact: No

Identifiers Released: No

History: New Research Project

VSAC Discussion: A comment was made that it was not clear how the Death Statistical Master file would be used in the project as the requester plans to link it to their in-house internal data files to create controls. The controls would be used to understand burdens and costs, but there isn't any information in the death files that would meet that purpose. Laura clarified that the DSMF would be used to find out who participated and died as they have no other way of knowing that, their electronic health record, not reflected unless they died in the hospital or unless someone in the program that is notified.

VSAC Recommendation(s): Approve the data request.

VSAC Motions: Jonathan Teague motioned to recommend approval of the data request. David Grant seconded the motion.

VSAC Vote: The Committee members voted in favor of recommending approval of the data request. There were no oppositions. Motion carried.

The fourth project reviewed by the Committee was:

Project Title: "Prenatal and Neonatal Biologic Markers for Autism"

Principal Investigator(s): Gayle C. Windham, PhD, CDPH
Environmental Health Investigations Branch

Project Type: New Project

CPHS Approval: Approved

Project No.: 12-08-0662

Expiration: August 30, 2013

File(s) Requested: 2000-2003 Birth Cohort File (select variables), 2000-2003 Birth Statistical Master File (select variables)

Requested Identifiers: BC: Name, Certificate Number; BSMF: Name, Certificate Number, and Address

Personal Contact: No

Identifiers Released: No

History: New Research Project

VSAC Discussion: A question arose as to who the principal investigator was? Dr. Croen was listed as the principal investigator on the protocol. Dr. Windham's CV was not included in the protocol.

VSAC Recommendation(s): Approve the data request.

VSAC Motions: Deborah Williams motioned approval of the data request. Jonathan Teague seconded the motion.

VSAC Vote: Committee members all voted in favor of recommending approval of the data request. There were no oppositions. Motion carried.

The fifth project reviewed by the Committee was:

Project Title: "Linkage of Medi-Cal Administrative Data to California Birth Cohort"

Principal Investigator(s): Aldona Herrndorf, MPH, Department of Health Care Services, Research and Analytics Branch

Project Type: New Project

CPHS Approval: Approved

Project No.: 13-02-1122

Expiration: N/A

File(s) Requested: 2007-2010 Birth Cohort File (select variable)

Requested Identifiers: Certificate Number only

Personal Contact: No

Identifiers Released: No

History: New Research Project.

VSAC Discussion: Laura's comment was this is a request to link the Birth Cohort with administrative data for Medi-Cal. This is not a

research request. Requestors suggest that they will use linked data for future research – should they be able to come back to VSAC for review of these projects?

VSAC Recommendation(s): Approve the data request. The Committee decided to change the recommendation to include the stipulation that research projects come back for VSAC review after review of the sixth project.

VSAC Motions: David Grant motioned to recommend the approval of the data request. Jonathan Teague seconded the motion.

VSAC Vote: Committee members all voted in favor of recommending approval of the data request. There were no oppositions. Motion carried.

The sixth project reviewed by the Committee was:

Project Title: "Linkage of Medi-Cal Administrative Data to the Death Statistical Master File"

Principal Investigator(s): Aldona Herrndorf, MPH, Department of Health Care Services, Research and Analytics Branch

Project Type: New Project

CPHS Approval: Approved

Project No.: 13-02-1102

Expiration: N/A

File(s) Requested: 2009-2011 Death Statistical Master file (select variables)

Requested Identifiers: Name, SSN

Personal Contact: No

Identifiers Released: No

History: New Research Project

VSAC Discussion: Laura's comment was this a request to link the DSMF with administrative data for Medi-Cal rather than a research request. Requestors suggest that they will use linked data for future research – should they have to come back to VSAC for review of these projects? They would need to be aware they would need to come back if it is research. As it is for data linkage, program review and evaluation is fine.

VSAC Recommendation(s): Approve the data request with the stipulation that research projects come back for VSAC review.

VSAC Motions: Jonathan Teague motioned to review the protocol after we receive CPHS approval. Deborah Williams seconded the motion. Jonathan Teague motioned to approve with stipulation that research projects comes back for VSAC review.

VSAC Vote: Committee members all voted in favor of recommending approval of the data request. There were no oppositions. Motion carried.

The seventh project reviewed by the Committee was:

Project Title: "Effects of Increased Economic Resources on Weight-Related Health"

Principal Investigator(s): Jessica Jones-Smith, Johns Hopkins Bloomberg School of Public Health

Project Type: New Project

CPHS Approval: Approved

Project No.: 12-11-0931

Expiration: January 3, 2014

File(s) Requested: 1987-2011 Birth Statistical Master File (select variables)

Requested Identifiers: Address Only

Personal Contact: No

Identifiers Released: No

History: New Research Project

VSAC Discussion: No discussion

VSAC Recommendation(s): Approve the data request.

VSAC Motions: Jonathan Teague motioned to recommend approval of the data request. David Grant seconded the motion.

VSAC Vote: Committee members all voted in favor of recommending approval of the data request. There were no oppositions. Motion carried.

The eighth project reviewed by the Committee was:

Project Title: "Organic Pollutants and Breast Cancer Risk: Chemical Old and New Project Type"

Principal Investigator(s): Peggy Reynolds, PhD, Cancer Prevention Institute of California

Project Type: Continuing Project with Changes to Protocol – additional data requested

CPHS Approval: Approved

Project No.: 12-09-0732

Expiration: December 6, 2013

File(s) Requested: Special data request of 2,800 records from 1980-1995 (select variables) Data will come from the CDPH Issuance and Preservation Branch.

Requested Identifiers Street Address, City, State and Zip Code

Personal Contact: Yes

Identifiers Released: No

History: Previous Data Request.

VSAC Discussion:

The requester is seeking approval to obtain address information for previously acquired state file numbers for records from 1980 to 1995 as addresses were not included in statistical master files for those years.

VSAC Recommendation(s): The committee agreed to recommend approval to access the addresses for state file numbers which the requester already has.

VSAC Motions: Jonathan Teague motioned to recommend approval of the data request. Deborah Williams seconded the motion.

VSAC Vote: Committee members all voted in favor of recommending approval of the request. There were no oppositions. Motion carried.

The ninth project reviewed by the Committee was:

Project Title: "Los Angeles Health Overview of a Pregnancy Event (LAHOPE)"

Principal Investigator(s): Shin Margaret Chao, MPH, PhD, Los Angeles County Department of Public Health

Project Type: Continuing Project not previously reviewed by VSAC – additional data requested

CPHS Approval: Approved

Project No.: 12-10-0828

Expiration: November 3, 2013

File(s) Requested: YTD Ad Hoc Birth Data File (select variables)

Requested Identifiers: California identifiers only

Personal Contact: Yes

Identifiers Released: No

History: Previous Data Request

VSAC Discussion: This project has not previously been reviewed by VSAC as the State Registrar at that time waived VSAC review with the recommendation that extensions of the project should go through normal VSAC review procedures. Laura has not had a chance to review this protocol.

VSAC Recommendation(s): Approve the data request.

VSAC Motions: Jonathan Teague motioned to recommend approval of the data request. David Grant seconded the motion.

VSAC Vote: Committee members all voted in favor of recommending approval of the data request. There were no oppositions. Motion carried.

The tenth project reviewed by the Committee was:

Project Title: "Los Angeles Mommy and Baby (LAMB) Project"

Principal Investigator(s): Shin Margaret Chao, MPH, PhD, Los Angeles County Department of Public Health

Project Type: Continuing Project not previously reviewed by VSAC –

additional data requested

CPHS Approval: Approved

Project No.: 10-12-02 **Expiration:** February 7, 2014

File(s) Requested: YTD Ad Hoc Birth Data File (select variables)

Requested Identifiers: California identifiers only

Personal Contact: Yes

Identifiers Released: No

History: Previous Data Project.

VSAC Discussion:

This was another project in which the State Registrar previously waived VSAC review on the condition that it would be presented to VSAC for further extensions. Laura has not had a chance to review this protocol.

VSAC Recommendation(s): Approve the data request.

VSAC Motions: Deborah Williams motioned to recommend approval of the data request. Jonathan Teague seconded the motion.

VSAC Vote: Committee members all voted in favor of recommending approval. There were no oppositions. Motion carried.

The eleventh project reviewed by the Committee was:

Project Title: "Suicide Mortality and Veteran Status"

Principal Investigator(s): Robert M. Bossarte, PhD, Department of Veterans' Affairs, Center for Excellence for Suicide Prevention, Canandaigua VA Medical Center

Project Type: New Project

CPHS Approval: Approved

Project No.: 12-07-0503

Expiration: August 2, 2013

File(s) Requested: 1999-2009 Death Statistical Master File (select variables)

Requested Identifiers: Name, SSN

Personal Contact: No

Identifiers Released: No

History: Previous Data Request.

VSAC Discussion: No discussion.

VSAC Recommendation(s): Approve the data request.

VSAC Motions: Jonathan Teague motioned to recommend approval of the data request. Deborah Williams seconded the motion.

VSAC Vote: Committee members all voted in favor of recommending approval of the data request. There were no oppositions. Motion carried.

F. ITEMS FOR DISCUSSION: Krista asked the Committee to refer to Item F, Recap of Data Requests Approved in the Vital Statistics Unit, Attachment 3. There were twenty data requests that did not require VSAC/VRPAC review were reviewed and approved by the Health Information and Research Section.

G. PUBLIC COMMENT: There were three members of the public attending the meeting.

Dr. Mary Karpos provided introductory information on herself:

- She taught research methods for 20 years at Vanderbilt University.
- She is currently the chairperson for her state (Tennessee) IRB
- She grants and denies research application.

The purpose for her speaking to the committee is to request initiation of a resolution regarding the violation of human subjects in coercion and forced participation research. This manner is under the jurisdiction as an advisory committee as well as those who are state employees who oversee this process. She wanted to draw attention that CPHS made application with the US Health and Human Services for and received child assurance pursuant to Part 46 Title 45, checking items B, C, and D of code of Federal Regulations.

The California Department of Public Health has disseminated to all county registrars a handbook for birth certificate information.

The attachment on page 5 depicts the form for certificate for live births and confidentiality information for public health use only. On the bottom of the page, the privacy notification indicates a failure to comply would be a misdemeanor. She does not object to providing information for the certificate of live birth and acknowledge that a

failure to do so would be a misdemeanor; however, no such misdemeanor exists for failing to complete the confidential information for public health use form and respondents should not be coerced into completing the form. This coercion is a direct violation of federal regulation relating to human subject research part 46 and 45 which requires consent and right of refusal to provide information for research purposes. She became aware of this forced research participation when preparing for the birth of her son who is due September 6 in California.

She has spoken to several people including Karen Roth about Health and Safety Code 102445 as it clearly states that the form should be labeled confidential information for public health use only. The parents or informant should be informed of the purposes for collecting the information, the confidential nature, and notified that completing the specific items are voluntary.

She was told that Section 102445 has no bearing on the matter and is superseded by other California codes.

She feels she cannot move forward and is moving to file an appeal with our agency and with the US Department of Health and Human Services to ask them to audit the Birth Registration Handbook to determine if we are compliant with Part 46 and Title 45, items (b), (c), and (d). Dr.Kampos is requesting the handbook and all instructions that instruct anything but a voluntary response be withdrawn and the immediate dissemination of directive of our signature that assures all counties understand the right of refusal as it relates to completing the confidential information for public health form.

Karen Roth stated that the content of the birth certificate is required under Section 102425. There are some things that are optional – race and ethnicity, education, mother and father’s occupation. Other than that, those items are required by state law. The issuance of the handbook is state law. It is issued to all health departments and is provided to them to provide uniform guidance. Health and Safety Code 103775 states every person except a parent and informant is responsible for supplying information and those who fails or refuses to file correct information, or provides false information is guilty of a misdemeanor. There is a duty to furnish information (Section 102135) – all physicians, informants, funeral directors, clergy, judges, or other persons who have knowledge of the facts shall supply upon the prescribed forms any information they possess. The parents are not the ones who register the birth; it is the hospital administrator which is in state law under 102405. Regarding surrogates, we did establish procedures back in 1999, and sent a letter to the counties. We worked closely with surrogate attorneys to put the procedures in place. The handbook and an updated letter to the counties were done

in 2004 stating the information that was required. What we are looking for is the confidential information of the mother who is giving birth to the child.

Dr.Kampos' response was that a woman is required to:

- State when her last period was
- When her last prenatal visit was
- The number of prenatal visits
- Expected source of payment for delivery
- Concurrent illnesses she may have
- If she terminated any pregnancies.

None of these relate to the issuance of a birth certificate, this is solely for the purpose of gathering information and performing research.

She said will continue to investigate if we are following federal regulations.

1. Sun Lee wanted copies of the following protocols: Project 8: Persistent Organic Pollutants and Breast Cancer Risk: Chemical Old and New and Project 9: Los Angeles Health Overview of a Pregnancy Event (LAHOPE). She had questions about Project 6: Linkage of Medi-Cal Administrative Data to the Death Statistical Master File. She asked if data applicants must provide information about in-staff or contractors. Krista replied that we do need to have the names of the people who will be working with the data.

H. AGENDA ITEMS: Krista asked the Committee if there were any agenda items for the next meeting. There were no agenda items.

I. MEETING ADJOURNMENT: Deborah Williams motioned to adjourn the meeting. Jonathan Teague seconded the motion. Committee members all voted in favor of adjourning the meeting at 10:48 A.M.